

1839-93

12/11/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 11 2013

Mr. Thomas W. Isaac
Regulatory Analyst
Stepan Company
22 W. Frontage Rd.
Northfield, Illinois 60093

Subject: **Power Detergent/Disinfectant**
EPA Registration Number 1839-93
Notification Application Dated November 13, 2013
EPA Received Date November 13, 2013

Dear Mr. Isaac:

This will knowledge receipt of your notification, submitted under the provisions of FIFRA section 3c 9. Based on a review of the submitted material the following comment apply.

Proposed Amendment:

- Revise net contents statement to allow for multiple count packets

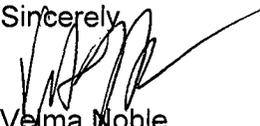
General Comments:

Based on a review of the material submitted, the following comment apply:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,


Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1839-93	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Powder Detergent/Disinfectant	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Stepan Company 22 W. Frontage Rd. Northfield, IL 60093 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Revised the NET CONTENTS statement to allow for multiple count packets (see pages 1,2,5 & 6)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 1.5 ozs.	No. per container multiple	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2-7.5 lbs.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Thomas W. Isaac	Title Sr. Regulatory Specialist	Telephone No. (include Area Code) (847)501-2309
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Thomas W. Isaac</i>	3. Title Sr. Regulatory Specialist	
4. Typed Name Thomas W. Isaac	5. Date November 13, 2013	



November 13, 2013

Document Processing Desk (NOTIF)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Antimicrobials Division (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTN: Ms. Velma Noble
PM-31
Regulatory Management Branch I

RE: Powder Detergent/Disinfectant
EPA Reg. No. 1839-93

Dear Ms. Noble:

This NOTIFICATION proposes the following label revision:

- Revised NET CONTENTS statement to allow for multiple count packets (see pages 1,2,5 & 6)

Labels:

Five (5) copies of the proposed revised label are included. One copy is highlighted illustrating the proposed revision.

Should you have any questions concerning this notification, please contact me at (847) 501-2309 or via email: tisaac@stepan.com.

Sincerely,
STEPAN COMPANY

Thomas W. Isaac
Sr. Regulatory Specialist

Enclosures: EPA Form: 8570-1, Label (5 copies)

TWI:sif

058-13-TI-EPA-1839-93

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POWDER DETERGENT/DISINFECTANT

CLEANER
DETERGENT

DISINFECTANT
DEODORIZER

FUNGICIDE (against pathogenic fungi)
MILDEWSTAT (on hard inanimate surfaces)

* VIRUCIDE

Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)

(For Commercial and Institutional Use Only)-Optional

ACTIVE INGREDIENTS

Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈)
dimethyl benzyl ammonium chlorides7.95%

Alkyl (68% C₁₂, 32% C₁₄)
dimethyl ethylbenzyl ammonium chlorides.....7.95%

INERT INGREDIENTS84.10%

Total 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

(OPTIONAL) You may contact xxx/xxx-xxxx for emergency medical treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

See (side) (back) panel for additional precautionary statements.

EPA REG. NO. 1839-93
EPA EST. NO. 1839-IL-01

STEPAN COMPANY

22 West Frontage Rd.
Northfield, IL 60093

NOTIFICATION
Date Reviewed: 12/8/13
Reviewed By: REL

TOTAL NET CONTENTS: (X) lbs. (X) ozs.

(mandatory: must be expressed in avoirdupois pounds and ounces)

Optional: can also include total count and size

(X) Water Soluble Packets, Each Containing (1/2 oz, 1/8 oz, 1 oz, 1.5 oz or 5.75 grams) of product

EXAMPLES of NET CONTENTS

TOTAL NET CONTENTS: 2 lb. 13 oz.

30 Water Soluble Packets, Each Containing 1.5 oz. of product

45 water Soluble Packets, Each containing 1 oz. of product

90 Water Soluble Packets, Each containing 1/2 oz. of product

360 Water Soluble Packets, Each containing 1/8 oz. of product

221 Water Soluble Packets, Each containing 5.75 grams of product

TOTAL NET CONTENTS: 3 lb. 12 oz.

40 Water Soluble Packets, Each Containing 1.5 oz. of product.

TOTAL NET CONTENTS: 7 lbs. 8 oz.

80 Water Soluble Packets, Each Containing 1.5 oz. of product.

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DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Powder Detergent/Disinfectant is a phosphate-free formulation designed to provide effective cleaning, deodorizing, and disinfection specifically for hospitals, nursing homes, and other institutions where housekeeping is of prime importance in controlling the hazard of cross-contamination.

This product, when used as directed, is formulated to disinfect inanimate, hard non-porous surfaces such as walls, floors, sink tops, tables, and chairs. For larger areas such as operating rooms, patient care facilities, and restrooms, this product is designed to provide both general cleaning and disinfection.

Use this product to clean and disinfect hard, non-porous surfaces of personal protective safety equipment (PPE), athletic equipment (helmets, headgear) and non-medical breathing apparatus (respirators, gas masks).

This product deodorizes those areas which generally are hard to keep fresh smelling, such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms.

PACKETS – Tear open packet—follow label dilution instructions and discard opened packet according to label disposal instructions.

Water soluble packet—follow label dilution instructions by dropping packet directly into water. Do not remove packets before use. Store in cool dry place. Do not handle packets with wet hands.

DISINFECTION - To disinfect inanimate, hard non-porous surfaces add one (1/8 oz., 5.75 gm, 1/2 oz., 1 oz., 1.5 oz.) pre-measured packet of product or measure powder at the following use dilutions:

Add this amount of product:	1/8 ounce (3.55 grams)	5.75 grams	1/2 ounce	1 ounce	1 1/2 ounces
in warm water to make:	One Quart	52 ounces	1 Gallon	2 Gallons	3 Gallons

Stir gently to form a uniform solution. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes and then let air dry.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

DISINFECTION and CLEANING of NON-MEDICAL PERSONAL PROTECTIVE EQUIPMENT (PPE):

Pre-clean heavily soiled, hard, non-porous surfaces of the equipment prior to disinfecting. Add 0.5 oz. of (this product) (product name) to one gallon of water (or equivalent use dilution). Stir gently to form a uniform solution. Apply solution to the hard, non-porous surfaces of the equipment with a cloth, sponge, hand pump trigger sprayer or by immersion. Thoroughly wet all surfaces to be disinfected, allow to remain wet for 10 minutes. Wipe off any excess solution with a clean cloth, rinse the treated surface with potable water and let air dry prior to storage. The user must comply with all OSHA regulations (Code of Federal Regulations Title 20, Part 1910-134) for cleaning respiratory protection equipment.

PRECAUTION: Disinfection and cleaning at temperatures above 120°F will cause distortion of personal protection equipment (PPE) necessitating replacement.

BACTERICIDAL ACTIVITY - At the stated Disinfection dilution rate, this product exhibits effective disinfectant activity against the organisms: Pseudomonas aeruginosa PRD-10, Escherichia coli, Klebsiella pneumoniae, Salmonella (schottmuelleri) enterica, Salmonella (choleraesuis) enterica, Brevibacterium ammoniagenes, Streptococcus faecalis, Shigella dysenteriae, Staphylococcus aureus, Enterobacter aerogenes and meets all requirements for hospital use.

MILDEWSTAT - To control mold and mildew on pre-cleaned, hard, non-porous surfaces mix this product at the stated dilution rate for Disinfection. Apply solution with a mop, cloth, sponge or hand pump trigger sprayer making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth appears. At the disinfectant dilution rate, this product is also fungicidal against the pathogenic fungi Trichophyton mentagrophytes.

* **VIROCIDAL ACTIVITY** - This product, when used on environmental, inanimate, hard surfaces at the Disinfectant dilution rate, exhibits effective virucidal activity against HIV-1, Influenza A₂, Parainfluenza Type 1 (Sendai), Canine Distemper, Feline Pneumonitis, Vaccinia virus, Herpes Simplex Type 1, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV).

(optional statements to appear anywhere on the label)

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product (Product Name) has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product (Product Name) has demonstrated effectiveness against (Influenza A virus tested and listed on the label) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus.

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STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE OR DISPOSAL.

PESTICIDE STORAGE - Store in a dry place no lower in temperature than 50°F or higher than 120°F. Store in an area inaccessible to children.

(for products with industrial, institutional and commercial use sites)

CONTAINER DISPOSAL – Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container promptly after emptying.

(Containers 5 gallons or less)

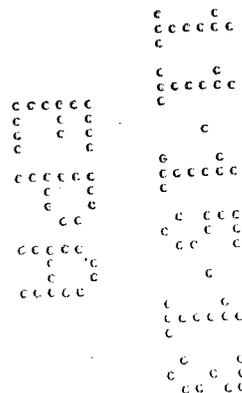
Triple rinse as follows: Fill container ¼ full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(Containers greater than 5 gallons):

Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

PACKET DISPOSAL - Do not reuse packet. Discard packet in trash.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.



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Packet Label:

**POWDER
DETERGENT/DISINFECTANT**

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides.....	7.95%
Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	7.95%
INERT INGREDIENTS	84.10%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See master label for additional precautionary statements
and use directions.

Disposal - Do not reuse empty packet. Wrap packet and put in trash.

EPA REG. NO. 1839-93
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road • Northfield, IL 60093

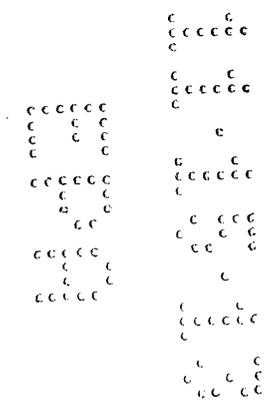
Mix contents in **1 gallon** of water.
NET WEIGHT CONTENTS: **½ ounce**

or
Mix contents in **2 gallons** of water.
NET WEIGHT CONTENTS: **1 ounce**

or
Mix contents in **3 gallons** of water
NET WEIGHT CONTENTS: **1.5 ounces**

or
Mix contents in **1 quart** of water.
NET WEIGHT CONTENTS: **1/8 ounce**

or
Mix contents in **52 ounces** of water.
NET WEIGHT CONTENTS: **5.75 grams**



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Water Soluble Packet Label:

POWDER DETERGENT/DISINFECTANT

ACTIVE INGREDIENTS

Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chlorides	7.95%
Alkyl (68% C ₁₂ , 32% C ₁₄)	
dimethyl ethylbenzyl ammonium chlorides	7.95%
INERT INGREDIENTS	<u>84.10%</u>
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

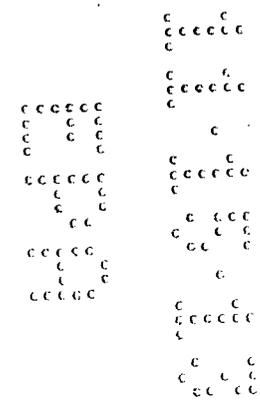
DANGER

See master label for additional precautionary statements and use directions.

EPA REG. NO. 1839-93
EPA EST. NO. 1839-IL-01

STEPAN COMPANY
22 West Frontage Road • Northfield, IL 60093

- Add one packet in **1 gallon** of water.
NET WEIGHT CONTENTS: **½ ounce**
- or
- Add one packet in **2 gallons** of water
NET WEIGHT CONTENTS: **1 ounce**
- or
- Add one packet in **3 gallons** of water
NET WEIGHT CONTENTS: **1.5 ounces**
- or
- Add one packet in **1 quart** of water.
NET WEIGHT CONTENTS: **1/8 ounce**
- or
- Mix contents in **52 ounces** of water.
NET WEIGHT CONTENTS: **5.75 grams**



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**Alternate Water Soluble Packet Label:
(for small 1" x 1" packets)**

**POWDER
DETERGENT/DISINFECTANT**

Quaternary Ammonium Chlorides

KEEP OUT OF REACH OF CHILDREN

DANGER CORROSIVE

See outer container for
Precautions and Directions.

EPA REG. NO. 1839-93

